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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,884	03/21/2002	R. Keith Frank	40999	4982

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THE DOW CHEMICAL COMPANY
INTELLECTUAL PROPERTY SECTION
P. O. BOX 1967
MIDLAND, MI 48641-1967

EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/088,884	Applicant(s) FRANK, R. KEITH	
	Examiner Brian S Kwon	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 10-18 are objected to because of the following informalities: Misspelling of word such as "aminoalkylenephophonate" is present. "aminoalkylenephophonate" should be corrected as "aminoalkylenephosphonate".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4 and 13 recite that the claimed amine moiety of the aminoalkylenephosphonate is represented by N-substituted imino group, $R-N=$, wherein R can be aliphatic or cyclic moiety. Further, the claims relate that the represented amine moiety, $R-N=$, is presented in $R-N(Alk-PO_3H_2)_2$. However, no N-substituted imino group, $R-N=$, can be derived from $R-N(Alk-PO_3H_2)_2$. This inconsistency causes unclarity of the subject matter. Applicants could obviate this rejection by correcting $R-N=$ to $R-N<$ (it is noted to applicants that above reasoning also applies to the instant disclosure (page 3, lines 18-24)).
3. Claims 10-18 provide for the use of one or more of the compounds of the group consisting of an aminoalkylenephosphonate, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

It is noted to applicants that for examination purpose, the use claims are interpreted as “method of minimizing loss of bone mineral in mammals”.

Claim Rejections - 35 USC § 101

4. Claims 10-18 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5 and 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Moore et al. (FUNDAMENTAL AND APPLIED TOXICOLOGY, 1990 April, 14 (3), 491-501).

The claims read on a method for minimizing loss of bone mineral density in mammals comprising administering an effective amount of aminoalkylenephosphonate or a pharmaceutically acceptable salt thereof. Further limitations include “at least one R-N(Alk-PO₃H₂)₂ group wherein R can be an aliphatic or cyclic moiety, and Alk is an alkylene group having from 1 to 4 carbon atoms” (claims 2 and 11); “at least two RR’N-Alk-PO₃H₂ group

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wherein R and R' can be, same or different, aliphatic or cyclic moiety, and Alk is an alkylene group having from 1 to 4 carbon atoms" (claims 3 and 12); "the nitrogen atoms in the amine moiety of the aminoalkylenephosphonate are partially or completely substituted by an alkylphosphonate" (claims 4 and 13); and "aminomethylenephosphate" (claims 5 and 14).

Moore teaches the use of N,N,N',N'-ethylenediaminetetramethylenephosphonate (EDITEMP.Na6) in reducing bone resorption (abstract; page 499, column 1, para. 2). The referenced N,N,N',N'-ethylenediaminetetramethylenephosphonate reads on every claimed limitation.

Although the instantly claimed method uses the different words to describe the referenced teaching, one of ordinary skill in the art must be able to immediately envisage that both words "minimizing loss of bone mineral" in the instant invention and "reducing bone resorption" in the reference are referring to the same therapeutic utility. Thus, the reference anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 6-9 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore et al. (FUNDAMENTAL AND APPLIED TOXICOLOGY, 1990 April, 14 (3), 491-501) in view of Jia (US 5902825) and applicants admitted prior arts of record (page 4, lines 14-19).

The teaching of Moore has been discussed in above 35 USC 102(b) rejection.

Jia teaches or suggests the use of a non-radioactive metal ion complexed with phosphonates including aminoalkylenephosphonates (e.g., EDTMP (interchangeably known as EDITEMPA), DOTMP, AMP) for the palliation of pain in patients having diseases of bone and/or bone joints (abstract; column 6, line 51 thru column 7, line 6; claims). Further, in column 6, lines 1-14, Jia teaches or suggests that said metal phosphate complexes interferes or blocks bone resorption caused by enzymes or abnormal osteoclastic cell activity, osteoblastic overactivity, as well as inflammatory within the joint region and on the bone surface; and acts an agent for preventing further destruction of the bone.

The applicant's admitted prior art discloses that the aminoalkylenephosphonates contemplated by the present invention are well known in the art.

The teaching of Moore differs from the claimed invention in the use of the specific aminoalkylenephosphonates such as PCTMP, BP2MP and AMPDMP in reducing bone resorption (or minimizing loss of bone mineral). To incorporate such teaching into the teaching of Moore, would have been obvious in view of Jia who teaches or suggests the use of aminoalkylenephosphonates (e.g., EDTMP, DOTMP, AMP) metal complexes for inhibiting bone resorption and preventing further destruction of the bone and the applicants admitted prior art of record that teaches or suggests the similar physiological characteristics of the claimed aminoalkylenephosphonates.

One having ordinary skill in the art would have expected as taught by combinations of Moore and Jia that either aminoalkylenephosphonates (e.g., EDITEMPA) or aminoalkylenephosphonates metal complexes would be effective in reducing bone resorption (or minimizing loss of bone mineral). Further, one having ordinary skill in the art would have expected as taught by Moore and Jia combination that DOTMP would have similar activities as EDITEMPA. Furthermore, one having ordinary skill in the art would have expected as taught by Moore, Jia and the admitted prior art that other known aminoalkylenephosphonates such as PCTMP, BP2MP and AMPDMP would have similar activities as EDITEMPA and DOTMP. One skilled in the art would be motivated to employ PCTMP, BP2MP and AMPDMP for reducing bone resorption (or minimizing loss of bone mineral) since it is expected to have similar activities to the other known members.

Conclusion

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7. No Claim is allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

**ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600**

A handwritten signature in black ink, appearing to read 'Zohreh Fay', with a large, sweeping loop at the end.